EMERGENCY RELIEF REQUESTED
Nos. 2025-1722 & 2025-1723

United States Court of Appeals
for the Federal Circuit

IN RE: ENTRESTO (SACUBITRIL/VALSARTAN)

NOVARTIS PHARMACEUTICALS CORPORATION,
Plaintiff – Appellee

v.

MSN PHARMACEUTICALS, INC., MSN LABORATORIES PRIVATE LIMITED, MSN LIFE SCIENCES PRIVATE LIMITED,
Defendants – Appellants

Appeal from the United States District Court of the District of Delaware
Civil Action Nos. 1:19-cv-02053-RGA & 1:20-md-02930-RGA, Hon. Richard G. Andrews

APPELLANTS' REPLY IN SUPPORT OF THEIR EMERGENCY MOTION FOR A RULE 8 ADMINISTRATIVE STAY PENDING APPEAL AND TO EXPEDITE

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MAY 9, 2025

CERTIFICATE OF INTEREST

Counsel for MSN certify under Federal Circuit Rule 47.4 that the following information is accurate and complete to the best of their knowledge:

1. **Represented Entities.** Provide the full names of all entities represented b undersigned counsel in this case.

MSN Pharmaceuticals Inc., MSN Laboratories Private Limited, MSN Life Sciences Private Ltd.

2. **Real Parties in Interest.** Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities.

None.

3. **Parent Corporations and Stockholders.** Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities.

None.

4. **Legal Representatives.** List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court.

STAMOULIS & WEINBLATT LLC: Stamatios Stamoulis, Richard Charles Weinblatt
DAIGNAULT IYER LLP: Ronald M. Daignault, Richard Juang

5. **Related Cases.** Other than the originating case(s) for this case, are there related or prior cases that meet the criteria under Fed. Cir. R. 47.5(a)?

Yes, see separately filed notice.

6. **Related Cases.** Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees).

Not applicable.

Dated: May 9, 2025 Respectfully Submitted,

/s/ Kevin E. Warner
Kevin E. Warner

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Other Authorities

Rules

TABLE OF ABBREVIATIONS

Abbreviation	Description
'659 patent	U.S. Patent No. 8,101,659, asserted in the district court proceedings and at trial.
ANDA	Abbreviated New Drug Application
D.I.	Docket Entry for *Novartis Pharmaceuticals, Inc. v. MSN Pharmaceuticals Inc.*, No. 1:19-cv-2053-RGA (D. Del.), unless alternative proceedings are subsequently listed.
Entresto I	*In re Entresto (Sacubitril/Valsartan) Patent Litigation*, No. 1:20-md-2930-RGA, 2023 WL 4405464 (D. Del. July 7, 2023)
Entresto II	*In re Entresto*, 125 F.4th 1090 (Fed. Cir. 2025)
FDA	United States Food and Drug Administration
MSN	MSN Pharmaceuticals Inc., MSN Laboratories Private Limited, and MSN Life Sciences Private Limited
MSN.Mot.	Appellants' Emergency Motion For A Rule 8 Administrative Stay Pending Appeal And To Expedite (D.I. 15 in *In re Entresto*, Appeal No. 25-1722 (Fed. Cir. May 2, 2025)
Novartis	Novartis Pharmaceuticals Corporation
Novartis.Opp.Br.	Novartis's Opposition To Motions For A Stay Pending Appeal Of The Portion Of Judgment Relating To 35 U.S.C. §271(e)(4)(A), For An Administrative Stay Pending That Motion's Consideration, And To Expedite Merits Briefing (D.I. 15 in *In re Entresto*, Appeal No. 25-1722 (Fed. Cir. May 7, 2025)

INTRODUCTION

Novartis wrongly characterizes MSN's post-judgment efforts as raising "new defenses" against Novartis by "rewrit[ing] history" to "delay implementation of this Court's January judgment." Novartis.Opp.Br.1; Novartis.Opp.Br.12. This appeal targets how the district court implemented *Entresto II*, 125 F.4th 1090 (Fed. Cir. 2025), in its April 1, 2025 Final Judgment—namely, its failure to align it with this Court's holding that the '659 patent does not claim valsartan-sacubitril complexes.

MSN does not need to try new issues. It only wants *Entresto II* enforced against *both* parties. The decision that the '659 patent does not "claim" the relevant complex—which all agree is the form of sacubitril and valsartan in Entresto®—had consequences. To Novartis's benefit, it justified reversing the district court's written description decision, reviving the '659 patent. That was unquestionably a change in the scope of legal rights associated with the patent. To MSN's and the public's benefit, *Entresto II*'s does-not-claim holding also means the '659 patent fails the test required for listing in the FDA's Orange Book. That listing is the sole legal basis for the Pediatric Exclusivity that Novartis insists requires resetting MSN's final ANDA approval. Novartis.Opp.Br.8. But by refusing to adjudicate whether the patent should be listed and refusing to vacate the relief provided under § 271(e)(4), the district court abdicated its responsibility to enforce all consequences of this

Court's *Entresto II* judgment.

Staying the district court's § 271(e)(4) FDA-approval reset order partially ameliorates the harm resulting from the district court's inaction. There is nothing "speculative" about risks of harm to the public and MSN if the current § 271(e)(4) order stay is lifted. Novartis.Opp.Br.2; Novartis.Opp.Br.21. Novartis *concedes* that resetting MSN's approval to "tentative" subjects MSN to "FDA procedures for reobtaining final approval," (Novartis.Opp.Br.1), confirming MSN's original point: resetting final approval risks MSN *not* timely launching its currently-approved generic Entresto® product on July 16, 2025, when everyone agrees no patent or regulatory exclusivities can block the launch. That harm is unquestionably avoidable with a stay pending appeal. Simultaneously, Novartis concedes that the district court's commercial launch injunction is "protecting Novartis's patent rights and associated regulatory exclusivity" through July 15, 2025, unless the district court's judgment is vacated before then. Novartis.Opp.Br.23.

MSN's final FDA approval thus should be preserved until this Court can determine whether its *Entresto II* decision prospectively precluded further remedies flowing from the '659 patent's Orange Book listing. Granting that relief during this appeal maintains the status quo in which MSN has not launched but maintains the

final approval of its ANDA.

ARGUMENT

I. MSN Properly Stated the Review Standards for MSN's Rule 8 Motion.

"[I]n considering whether to grant a stay pending appeal, this court assesses movant's chances for success on appeal and weighs the equities as they affect the parties and the public." *Standard Havens Products, Inc. v. Gencor Industries, Inc.*, 897 F.2d 511, 513 (Fed. Cir. 1990). The Third Circuit "review[s] a district court's decision on the likelihood of success de novo" when the dispute "involves a purely legal determination." *S.S. Body Armor I., Inc. v. Carter Ledyard & Milburn LLP*, 927 F.3d 763, 772-73 (3d Cir. 2019). MSN's Motion is entirely based on the legal consequences of this Court's *Entresto II* opinion.

MSN did not "[i]gnor[e] the standard of review." Novartis.Opp.Br.2. It recited the same standard *Novartis* offered to secure its injunction pending appeal after its district court loss—*de novo* review. *See* Add218 (Novartis urging this standard "without deference to the district court's ruling on any request" seeking relief pending appeal). De novo review applies because this Court is "not reviewing any district court decision or order." 20 Moore's Fed. Prac. Civil §308.40, at n.10 (2024) (citing *Kentucky v. Biden*, 23 F.4th 585, 593 (6th Cir. 2022)). The Novartis-cited *Medrad, Inc. v. MRI Devices Corp.*, 401 F.3d 1313, 1322 (Fed. Cir. 2005), states the review standard for Rule 59 and 60 judgments that would be applicable to

the *merits* appeal. At this Rule 8 stage, this Court should consider whether MSN has shown a likelihood that the district court erred below to warrant a stay while the merits appeal is pending.

II. The District Court Improperly Declined to Decide Whether the '659 Patent Satisfies Orange Book Listing Requirements.

Assessing MSN's chances for success on appeal and weighing the equities justify staying the lower court's § 271(e)(4) order.

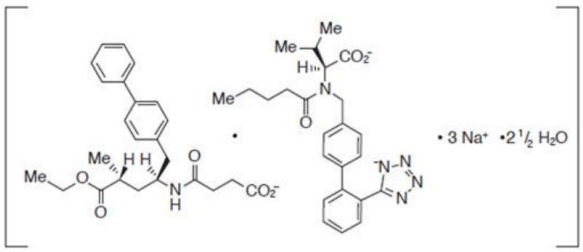
This Court reversed the district court's written description ruling because valsartan-sacubitril complexes present in Entresto® are *not claimed* by the '659 patent. *Entresto II*, 125 F.4th at 1097, 1099. Consequently, the '659 patent cannot "distinctly claim[] the drug as the invention" for Orange Book listing purposes. *Teva Branded Pharmaceutical Products R&D, Inc. v. Amneal Pharmaceuticals of New York, LLC*, 124 F.4th 898, 911 (Fed. Cir. 2024). That non-compliance renders the '659 patent ineligible to convey pediatric exclusivity or entitlement to 35 U.S.C. § 271(e)(4)(A) remedies. The district court exceeded its legal authority, and acted contrary to *Entresto II*, by awarding such remedies.

MSN timely explained—one day after the April 1, 2025 Final Judgment underlying this appeal issued—that Federal Rules 59(e), 60(b)(5), and 60(b)(6) gave the district court the tools needed to correct that problem, with or without a formal delisting counterclaim. MSN.Mot.9-11; *see also* Add162-Add164 ("We don't think there needs to be a counterclaim…"); *contra* Novartis.Opp.Br.16-19. Novartis

concedes the district court declined to decide the merits of whether the '659 patent satisfies the Orange Book listing standards this Court discussed in *Teva*. Novartis.Opp.Br.19 ("Although the district court had no need to reach the argument's merits…."). Even under an abuse of discretion standard, there is no district court ruling that Novartis can stand behind—and certainly no ruling that the district court deemed "meritless." Novartis.Opp.Br.1.

Novartis proposes regulatory exclusivity remains because the '659 patent claims "a combination of the 'active agents' valsartan and sacubitril." Novartis.Opp.Br.20. That ship has sailed. *Entresto II* decided that the '659 patent does not claim as the invention the specific valsartan-sacubitril *complex* undisputedly present in Entresto®. *Entresto II*, 125 F.4th at 1097, 1099. Even assuming the '659 patent *covers* Entresto® as an infringing combination, that is insufficient to show the '659 patent "claim[ed] the drug." *Teva*, 124 F.4th at 911 (this Court "reject[ed] Teva's argument that a patent claims the drug if it reads on the approved drug"). "Instead, a patent claims the drug when it particularly points out and distinctly claims the drug as the invention" to satisfy 21 U.S.C. § 355(b)(1)(A)(viii). *Id*. (emphasis added); *see also* 21 U.S.C. § 321(g)(1) (defining "drug" term). As a matter of law, the '659 patent does not *claim* the Entresto® complex.

Novartis then suggests that the complex everyone agrees is *in* Entresto® is not the drug approved *in* Entresto®. Novartis argues that Entresto®'s Orange Book listing, which under the heading "Active Ingredient[s]" says "SACUBITRIL; VALSARTAN," is determinative because it does not use the word "complex." Novartis.Opp.Br.20. That ignores the evidence MSN presented to the district court, including Entresto®'s *FDA-approved labeling*, which calls the drug "a complex" of sacubitril and valsartan, all depicted within a single set of brackets:



Add254. The same label defines the drug's molecular weight as 957.99 g/mol—the weight of the whole complex, *not* valsartan and sacubitril components. Add254. The labeling reiterates that only *after* oral administration will the complex "dissociate[] into sacubitril … and valsartan." Add254. That step is beyond the '659 patent claims, which are limited here to pharmaceutical compositions. *Entresto II*, 125 F.4th at 1094 (claim 1).

Nevertheless, this debate is foreclosed for Novartis because this Court already confirmed that "Entresto[®] includes valsartan and sacubitril in a specific form known as a 'complex,' which combines the two drugs into a single unit-dose-form…." *Entresto II*, 125 F.4th at 1093; *see also id*. at 1095 ("Novartis told the

Patent Office" the Entresto® drug was a "non-separate, complexed valsartan and sacubitril"); *Abbott Laboratories v. TorPharm, Inc.*, 300 F.3d 1367, 1377 (Fed. Cir. 2002) ("proposed labeling" with valproic acid/sodium valproate "acid/salt pair enclosed in parentheses" indicates a single subunit, not two separate drug species).

The "drug product," drug, and Entresto® active ingredient are limited to the single valsartan-sacubitril complex, which this Court emphasized in *Entresto II* is *not* what the '659 patent *claims*. Thus, the district court lacked legal authority to award remedies that derive from the '659 patent's Orange Book listing

III. *Entresto II* Legally Changed the Available '659 Patent Rights.

Whether or not *Entresto II* changed the law applicable to this case should be irrelevant. *Entresto II* means the '659 patent should not be listed in the Orange Book, and the district court's April 1 Final Judgment should be vacated at least as to the § 271(e)(4)(A) remedies. But MSN is also correct that there was a change in the law, constituting independent grounds to stay or vacate the § 271(e)(4)(A) remedy under Rules 59 and 60.

The district court's operational understanding when writing its post-trial invalidity opinion was that "[t]he written description requirement...requires that the specification 'clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented *what is claimed*.'" *Entresto I*, No. 1:20-md-2930-RGA, 2023 WL 4405464, at *21 (D. Del. July 7, 2023) (citing *Ariad Pharmaceuticals, Inc. v.*

Eli Lilly & Co., 598 F.3d 1336, 1351 (Fed. Cir. 2010)) (emphasis added). It was not confused about what the patent "covers" and how that relates to written description, as Novartis suggests. Novartis.Opp.Br.7. The district court found a lack of written description precisely because the inventors never possessed, and the '659 patent never described, valsartan-sacubitril ***complexes***. *Id*. at *21-22.

Entresto II reversed the written description finding because "*[t]hat complex*—not discovered until four years after the priority date of the '659 patent—*is not what is claimed*." 125 F.4th at 1098 (emphasis added); *id*. at 1099 ("the '659 patent does not claim valsartan-sacubitril complexes"); *id*. ("the patent does not claim as its invention valsartan-sacubitril complexes;" Novartis "obtained separate, later patents to such complexes").

Novartis thus lost patent rights when the district court understood the '659 patent to "claim" complexes and found invalidity; *Entresto II* restored them by clarifying that the patent does *not* "claim" complexes. The effect of that reversal thus plainly changed the legal force of the '659 patent. *See Google LLC v. EcoFactor, Inc.*, 92 F.4th 1049, 1054 (Fed. Cir. 2024) ("It is a bedrock principle of patent law that claims of a patent define the scope of a patented invention and the patentee's right to exclude….Claims are 'the life of the patent,' defining the limits of the patent's scope."). And that issue—the scope of what the '659 patent claims—

was central to the appeal leading to *Entresto II* and not waived by MSN. *Contra* Novartis.Opp.Br.13-14.

This Court has plenary authority to confirm that *Entresto II* changed the scope of the legal rights associated with the '659 patent, without deference to the district court on that question. *See Laitram Corp. v. NEC Corp.*, 115 F.3d 947, 951 (Fed. Cir. 1997) ("It offends common sense, moreover, to suggest that we must defer to what a trial judge inferred about *our* intent in what *we* wrote."). That then independently authorizes amending the judgment below.

IV. Harm to the Public and MSN Is Not Speculative.

Novartis concedes the real risk of uncertain commercialization timelines for MSN's generic product absent relief from this Court. *See, e.g.*, Novartis.Opp.Br.1 (recognizing MSN will need to "comply with any FDA procedures for reobtaining final approval"); *see also* Add279 (FDA: "A request for final approval that contains no new data, information, or other changes to the ANDA generally requires a period of 90 days for Agency review."). MSN stands ready to launch at the earliest available date, yet each day MSN remains unapproved after removing the patent and pediatric exclusivity barriers would deny the public the benefits of MSN's generic Entresto® product. That result directly flows from the § 271(e)(4)(A) relief Novartis seeks. *Contra* Novartis.Opp.Br.22.

Novartis says "enough is enough" and blames MSN for not accepting what MSN believes is the improper relief the district court awarded. Novartis.Opp.Br.2. Pursuing its legal right to maintain properly-awarded final approval through a rehearing petition to this Court, or seeking post-judgment relief below, are not actions that warrant punishment with an increased risk that MSN will not have approval to launch its product when everyone agrees Novartis's exclusivities extinguish. The true cause of MSN's harm is Novartis's prospective improper use, post-*Entresto II*, of the '659 patent for Pediatric Exclusivity to shelter itself from competition, coupled with the district court's unwillingness to correct its judgment perpetuating this legal error.

V. A Stay Will Not Injure Novartis, or Provide New Public Benefits.

Novartis nowhere suggests it will suffer any loss if the Court extends the stay through July 15. It instead argues that "both Novartis and the public have an interest in the post-appeal final judgment being enforced." Novartis.Opp.Br.22. But Novartis suffers no prejudice if the Court grants MSN's Motion. Resetting MSN's approval date lifts no burden on Novartis. It has (at its own choosing) continually monitored MSN's activities and has made no suggestion that it will stop doing so if this Court lifts the current stay.

Novartis claims the public "has a paramount interest in honoring the pediatric-exclusivity bargain." Novartis.Opp.Br.23. But that interest (if it lawfully exists

post-*Entresto II*) continues until this Court issues a merits decision favoring MSN or the district court's judgment is amended to exclude the § 271(e)(4)(A) relief, because MSN is not on the market until then.

As for Congressional intent, Novartis.Opp.Br.17, Novartis *knows* that denying MSN's motion may result in further delays of access to a drug that FDA properly determined was fit for marketing, (Novartis.Opp.Br.1), through illegitimate enforcement of Pediatric Exclusivity. Novartis cannot credibly contend that Congress intended to permit Novartis to delay generic entry beyond the Pediatric Exclusivity period that followed patent expiration when the whole point of the Hatch-Waxman Act was Congress trying "to eliminate" how the "premarket regulatory approval" processes "create[d] an effective extension of the patent term." *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 670 (1990). The injunction in place against MSN's launch realizes Congressional intent, protecting any contested patent or regulatory rights, while this dispute is litigated. What does *not* serve Congressional or public interests are district courts issuing remedies for patents non-compliant with the Orange Book listing statutes Congress wrote, especially when this Court's *Entresto II* decision made listing improper.

CONCLUSION

This Court should keep in place the current stay of the district court's Final Judgment to the extent it references 35 U.S.C. § 271(e)(4)(A), or otherwise orders

that MSN's final FDA approval be reset to a date not earlier than July 16, 2025, during the pendency of this appeal.

MSN further requested a merits briefing schedule that would permit this Court to rule on the merits of this appeal prior to July 15, 2025. Novartis refuses to cooperate, airily suggesting MSN should simply self-expedite. That practically ensures this Court cannot issue a merits decision until after July 15, 2025, with Novartis using its regular briefing schedule time—precisely the circumstances a stay pending appeal was designed to avoid. MSN would withdraw the request to expedite briefing if the Court grants this motion to stay pending appeal.

Dated: May 9, 2025

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE:
WORD COUNT AND TYPEFACE LIMITATIONS

Pursuant to Federal Rule of Appellate Procedure 27(d)(2)(A), this motion complies with the type-volume limitation. The undersigned hereby certifies that this motion contains 2519 words, excluding those parts of the motion that are exempted by Federal Rule of Appellate Procedure 32(f) and Federal Circuit Rule 32(b). As permitted by Federal Rule of Appellate Procedure 32(g)(1), the undersigned has relied upon the word count feature of the word-processing system used to prepare the Brief. This motion also complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6). The Brief has been prepared in a proportionally spaced typeface using Microsoft® Word 2019 in 14-point type size with Times New Roman font.

Dated: May 9, 2025

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